REMARKS/ARGUMENTS

Claims 38-50 and 54-59 have been examined. Applicants note with appreciation the allowance of claim 54. Claims 40, 42, 43, 45, and 56 have been amended to expedite prosecution of the present case. Claim 55 has also been amended. Claims 1-36 have been canceled. Re-examination and reconsideration of pending claims 38-50 and 55-59 are respectfully requested.

As an initial matter, Applicants request that the Examiner send confirmation of the consideration of the references cited in the Information Disclosure Statement filed by Applicants on October 24, 2003.

Restriction Requirement

Applicants have canceled claims 1-36 without prejudice pursuant to a restriction requirement. Applicants reserve the right to pursue patent protection for these inventions in a subsequently filed application.

Double Patenting

Claims 54-59 were rejected under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claims 52-59, 61, and 62 of U.S. Patent Application No. 09/783,254 (although the Office Action on page 1 refers to U.S. Patent Application No. 09/782,804, which is the present application's serial number, Applicants believe that U.S. Patent Application No. 09/783,254 was the intended application). A terminal disclaimer is being filed herewith to obviate this nonstatutory double patenting rejection.

Rejection under 35 U.S.C. §102

Independent claim 55 has been rejected under 35 U.S.C. §102 as allegedly being anticipated by U.S. Patent No. 6,506,437 issued to Harish et al. Such a rejection is respectfully traversed.

Independent claim 55 recites in part "releasing methylprednisolone and at least one other substance in addition to methylprednisolone from the prosthesis when implanted in the blood vessel, wherein the at least one other substance comprises mizoribine." This positive recitation of releasing mizoribine has not been reasonably shown or suggested by the cited art.

As the Examiner certainly knows and appreciates, a single cited art reference must teach each and every element of the claim to establish anticipation under 35 U.S.C. §102. M.P.E.P. §2131; *In re Royka*, 180 U.S.P.Q. 580 (CCPA 1974) ("All words in a claim must be considered in judging the patentability of that claim against the prior art."). The Court of Appeals for the Federal Circuit has held that, "the identical invention must be shown in as complete detail as is contained in the .... claim." *Richardson v. Suzuki Motor Co.*, 9 U.S.P.Q.2d 1913, 1920 (Fed. Cir. 1989).

The Harish et al. reference fails to teach releasing mizoribine, much less the combined release of methylprednisolone and mizoribine, as presently claimed by claim 55. Applicants request that if the present rejection is maintained, the Examiner show or explain where the Harish et al. patent reference describes or suggest such limitations. Absent such a showing, Applicants respectfully request withdrawal of this rejection and allowance of independent claim 55.

Rejection under 35 U.S.C. §103

Independent claim 38 has been rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Harish et al. Such a rejection is respectfully traversed.

Independent claim 38 is directed at a method for inhibiting restenosis comprising implanting a vascular prosthesis in the blood vessel and releasing methylprednisolone from the

prosthesis. In particular, claim 38 requires that the rate of release of methylprednisolone be in a range from 5 μg/day to 200 μg/day.

As the Examiner certainly knows and appreciates, *prima facie* obviousness requires that the prior art references, alone or in combination, teach or suggest all the claim limitations. M.P.E.P. § 2143.03; *In re Royka*, 180 U.S.P.Q. 580 (CCPA 1974). In the instant case, the claimed rate of release of claim 1 has not been reasonably disclosed or suggested by the Harish et al reference. Secondly, no suggestion or motivation, either in the cited reference or in the knowledge generally available to one of ordinary skill in the art, has been cited by the Examiner for the proposed modification of the reference teaching so as to produce the claimed invention. M.P.E.P. § 2143.01; *In re Fine*, 5 U.S.P.Q.2d 1596 (Fed. Cir. 1988).

As the Examiner has already acknowledged, "Harish et al. patent fails to disclose the rate which the therapeutic agents are released from the stent as claimed in claims 38-41 and 56". Office Action, page 3. Harish et al. is directed to methods of coating an implantable device, such as a stent or a graft, having a plurality of depots formed in a surface thereof. An exemplary method includes applying a composition including a polymer and a solvent to the implantable device proximate to the depots. The compositions employed in the methods may include one or more therapeutic substances. Among a laundry list of agents that can be employed as the therapeutic substance in the composition, Harish et al. names methylprednisolone. However, the Harish et al. reference fails to disclose or suggest the release rate of any therapeutic agent, let alone the specific release rates for methylprednisolone as claimed.

Secondly, based on the Harish et al. reference, one of ordinary skill in the art would not have been reasonably motivated to modify this teaching so as to produce Applicants' claimed methodology. The Examiner asserts that "[i]t would have been obvious to one having ordinary skill in the art at the time the invention was made to have the rate which the therapeutic agents are released from the stent as claimed in claims 38-41 and 56, since it has been held that where the general conditions of claims are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art." Office Action, page 3 (emphasis added).

Applicants point out that the Examiner bears the initial burden of factually establishing and supporting any *prima facie* conclusion of obviousness. *In re Rinehart*, 189 U.S.P.Q. 143 (CCPA 1976); M.P.E.P. § 2142. If the Examiner does not produce a prima facie case, the Applicant is under no obligation to submit evidence of nonobviousness. *Id.* In the instant case, the Examiner has not pointed to any evidence in the Harish et al. reference which teaches or suggest its modification. As noted above, Harish et al. makes no mention of any general conditions regarding the release rate of any therapeutic agent, let alone the specifics of release rates for methylprednisolone as claimed. See *In re Zurko*, 59 U.S.P.Q.2d 1693 (Fed Cir. 2001) ([I]n a determination of patentability .... the Board cannot simply reach a conclusion based on its own understanding or experience - or on its assessment of what would be basic knowledge or common sense. Rather, the Board must point to some concrete evidence in the record in support of these findings).

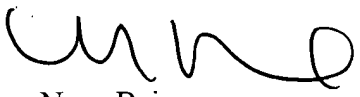
Applicants request, if the present rejection is maintained, that the Examiner show or explain where the Harish et al. reference provides the requisite motivation to modify the teaching so as to produce Applicants' claimed release rates for methylprednisolone. Absent such a showing, Applicants respectfully request withdrawal of this rejection and allowance of independent claim 38 (and dependent claims 39-50 and 56-59).

CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance and an action to that end is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 415-576-0200.

Respectfully submitted,



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